REMARKS

This Amendment and Remarks are filed in response to the First Office Action dated May 10, 2007 wherein all pending claims stand rejected.

Examiner's Response to Applicants Election

Examiner finds Applicant's argument that if the device of the invention comprises a composition of the invention, then the composition including all its components should also be searched, not persuasive for the reasons of record.

Applicant's argument that both the film and foam are attached to the device of the invention and if the device of the invention is found patentable, both the film and foam species will also be found to be patentable, is deemed to be persuasive.

Applicant's statement is being construed as evidence of obviousness with respect to the film and foam species. The election requirement is therefore withdrawn.

Applicant's argument that polymers albeit they might be chemically different typically behave in the same way when they have the same function in the mucosal composition is deemed persuasive. Thus, the polymer species election requirement is hereby withdrawn.

Applicant's argument that when formulated as a composition, the therapeutically effective agents in all drug groups have the same or similar release properties is deemed persuasive. This election requirement is also withdrawn.

Applicant's argument that the epithelium tissue in all these organs or cavities in connection with the topical drug delivery sites is the same or similar and that the released drug formulated for a transmucosal delivery will be delivered through the mucosal tissue regardless where such mucosal tissue is located is deemed persuasive. Thus, the election requirement with respect to the topical drug delivery site species is hereby withdrawn.

Applicant's argument that to elect one element for search will also discover other components present in a composition (or

subcomposition) is not deemed persuasive in view of the multiplicity of elements or ingredients encompassed by the instant invention and the reasons of record. This election of species requirement is maintained.

The Restriction/Election requirements are made final for the reasons stated above.

Applicants appreciate Examiner's withdrawal of restriction requirement concerning film and foam and species requirement concerning the polymers, drugs and mucosal tissues.

Status of the Claims

Claims 29-46, currently pending in this application are canceled and the new claims 47-60 are added. Support for these claims are found in the specification as indicated below. No new matter is added.

Claim 47 is supported in the specification page 1, lines 20-24(1:20-24) and 1:32-36 for solid, semi-solid or liquid foam or film devices, 2:1-12 for non-film or non-foam devices made of different material, 23:30-35 and page 24:1-35, for polymers.

Claim 48 is supported on page 33, lines 2-10.

Claim 49 is supported on page 33, lines 11-36, page 34 and page 35, lines 1-11.

Claim 50 is supported on page 7, lines 19-27.

Claim 51 is supported on page 23, lines 30-35 and page 24.

Claim 52 is supported on page 25 and 26, Table 1.

Claim 53 is supported on page 5, lines 30-36.

Claim 54 is supported on page 26, lines 16-32 for mucoadhesive agents, page 27, lines 15-36, pages 28-30, for penetration enhancers, page 30, lines 236 and page 31, lines 1-10 for release modifiers.

Claim 55 is supported on page 26, lines 7-15.

Claim 56 is supported on page 22, lines 15-33.

Claim 57 is supported on page 7, lines 19- 27

Claim 58 is supported on page 12, lines 27-31.

Rejections under 35 USC 112, Second Paragraph

The following is a quotation of the second paragraph of 35 use 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Claim 46 refers to the "[t]he composition of claim 45. To the extent that this claim is directed to a "composition," it lacks proper antecedent basis as claim 45 from which it depends is directed to a device. This claim is deemed to be indefinite because it fails to concisely define what applicant's deem as the invention.

For purposes of examination, claim 46 will be treated as a device.

Applicants canceled claim 46. Thus the rejection is moot.

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937,214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d

528; 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) or 1.321 (d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3. 73(b).

Claims 29-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-27 of US Patent 6,905,701 B2 ('701). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims. In particular, claim 24 of '701 is directed towards a medicated intravaginal device for a transmucosal delivery of bisphosphonates to the general circulation. In view of the fact that the treatment populations overlap, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant invention with a reasonable expectation of success. Thus, claims 29-46 are deemed obvious variants of the limitations of the patented subject matter claimed in '701.

Applicants disagree. Upon stricter review Examiner will find that the '701 patent contains different limitations related to the amount of the mucoadhesive agent needed for release of bisphosphonates from the vaginal device. Namely, the amount disclosed in the '701 patent is limited to between 0.01 and 5% of hydroxypropyl methylcellulose. This amount has been found sufficient for delivery of bisphosphonates.

Applicants respectfully submit that the current invention is not subject of double patenting. Moreover, as seen in the enclosed

declaration by Mr. Richard J. D'Augustine, the current invention and the '701 patent are commonly owned and both have at least one common inventor.

However, should Examine find that all other issues are resolved and the only issue is filing of the terminal disclaimer in the current case over the '701 patent, applicants will be willing to do so.

For the same reasons stated above, claims 29-46 are similarly deemed to be obvious variants of the limitations of the patented subject matter of claims 21-33 of U.S. Patent 6,982,091 ('091).

Applicants disagree. However, in the interest of advancing the examination, Applicants submit herewith a fully executed Terminal Disclaimer.

Examiner further argues that, in addition, claims 29-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following:

Claims 49-54, 55, 57-79 of copending Application No. 10/335,759; claims 1-15 of copending Application No. 11/126,863, claims 45-53 of copending Application No. 11/208,209, claims 1-55 of copending Application No. 11/180,076, claims 1-14 of copending Application No. 10/654,145, and claims 20-23 of copending Application No. 11/522,126, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of each other for essentially the same reasons stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Applicants disagree. However, in the interest of advancing the examination, Applicants submit herewith fully executed Terminal Disclaimers to the pending applications Ser. Nos.: 10/335,759; 11/126,863, 11/208,209, 11/180,076, 10/654,145, 10/335,759 and 11/522,126, respectively.

Applicants, however, cannot identify the pending application Ser. No. and 10/654,145 as a copending application.

Applicants further submit the Terminal Disclaimer to disqualify the issued patent 6,086,909 commonly owned by the Applicant's assignee and also submit the Statement by the Assignee.

Rejections under 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-46 are rejected under 35 USC 102(b) as being anticipated by Harrison et al. (US Patent 6,086,909),

Harrison et al. (6,086,909) teach devices, compositions and methods for treating dysmenorrhea by intravaginal administration of therapeutic and/or palliative drugs to the uterus (column 1, lines 13-16). Harrison et al. teach controlled release drug delivery system in the form of, for example, a tampon-like device, vaginal ring, pessary, tablet, paste, suppository, vaginal sponge, bioadhesive tablet, bioadhesive microparticles, cream, lotion, foam, ointment, or gel (column 9, lines 5-67). Harrison et al. teach various tampon like devices which can be used to deliver drugs for the treatment of dysmenorrhea wherein the drug is incorporated into the device via numerous methods (column 9, lines 29-34). Specifically, the drug can be incorporated into a gel-like

bioadhesive reservoir in the tip of the device, or the drug can be in the form of a powdered material positioned at the tip of the tampon, or the drug can also be dissolved in a coating material which is applied to the tip of the tampon, or the drug can be incorporated into an insertable suppository which is placed in association with the tip of the tampon (column 9, lines 36-45).

In Figure 6, the tampon device includes a distal porous foam section, which is preferably a soft, light weight, physiologically inert foam material of polyurethane, polyester, polyether, or other material such as collagen (column 10, lines 28-40).

Harrison et al. invention is directed to the delivery of drugs to the uterus using medicated intrauterine tampon; the device allows delivery of the drug intravaginally in lower concentrations than those need for systemic treatment and thus provides for lower systemic concentration and fewer side effects (column 1, lines 16-21). In one aspect, the invention provides a method for treating a human female suffering from dysmenorrhea comprising contacting the vaginal epithelium of the female with a pharmaceutical agent selected from the group consisting of nonsteroidal anti-inflammatory drugs, anti-prostaglandins, prostaglandin inhibitors, COX-2 inhibitors, local anesthetics, calcium channel blockers, potassium channel blockers (column 1, line 66 to column 2, line 16). Harrison et al. teach that non-limiting examples of nonsteroidal anti-inflammatory drugs suitable for practice of the invention include ketorolac (column 2, lines 17-21); see also Example 4 at columns 16-18.

Harrison et al. disclose methods for combining the pharmaceutical agent with a drug delivery system for intravaginal delivery of the agent; drug delivery system include a tampon device, vaginal ring, pessary, tablet, vaginal suppository, vaginal sponge, bioadhesive tablet, bioadhesive microparticle, cream, lotion, foam, ointment, solution and gel (column 2, second full paragraph). In one embodiment, a tampon device is sheathed in a thin, supple, non-porous material such as a plastic film or a coated gauze that surrounds the absorbent tampon material like a skirt and opens like an umbrella when it comes in contact with the vaginal environment (column 3, lines 55-67).

Harrison et all. teach a controlled release drug delivery system comprising non-limiting biocompatible excipient for applying the

agent including a lipophilic carrier or a hydrophilic carrier e.g. polyethylene glycol; muco-adhesive agents such as alginate and pectin; and penetration enhancers e.g. bile salts, organic solvents, ethoxydiglycol, or interesterified stone oil (column 2, third full paragraph). In certain embodiments, the excipient comprises between about 60 to 90% by weight lipohilic carrier, between about 5 to 25% mucoadhesive agent, and between abut 5 to 20% penetration enhancer (column 2, lines 60-67). In another embodiment, the formulation comprise between about 5-20% sorption promoter (column 8, lines 31-34). Thus, the claimed invention is anticipated by Harrison et al. because the limitations of the instant invention overlaps with Harrison et al. for the reasons stated above.

Applicants disagree. Anticipation rejection must contain all aspect of the anticipated invention. Applicants respectfully point out that such is not a case here, particularly not in view of the new claims.

The new claims are directed to a foam or film device that is a stand alone device made of specifically identified substrate polymers in combination with a therapeutically effective agent for topical delivery of a therapeutically effective agent to a vaginal, nasal, buccal, scrotal or labial epithelium. The device is prepared from a composition comprising at least one substrate polymer and the therapeutically effective agent. The foam or film device is preformed into a solid or semi-solid foam tampon, foam tablet, foam cylinder, foam or film strip, foam or film pad, foam or film pillow, foam or film tube, foam or film sheet, foam or film sphere, foam or film ring, foam bead or a single or double sided foam or film sheet, or is a liquid preparation that forms a foam or film layer device upon contact with an epithelial tissue or with a surface of non-foam or non-film device made of different material.

None of these features are disclosed in Harrison reference in the same combination and for the same use.

The subject foam or film device is directed to delivery of the drugs topically to the vaginal, buccal, nasal and scrotal epithelium.

Harrison only discloses delivery to and through the vaginal mucosa to the uterus. Harrison does not disclose the foams and films structures, not the film and foams in solid, semi-solid or liquid forms. Harrison does not disclose the polymers used for preparation of the foams or films as claimed herein and generally the Harrison reference is directed to devices and treatments of dysmenorrhea. The current invention is not so directed.

It is respectfully submitted that the current claims are not anticipated by Harrison reference that is, moreover, by the same inventor as Donald Harrison, the co-inventor of the current application and is co-owned by the same assignee.

Applicants respectfully request Examiner to withdraw the anticipation rejections.

Rejections under 35 USC 103

The following is a quotation of 35 U.S.C. 103(81) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art

under 35 U.S.C. 103(a).

Inventorship of all claims remain the same.

Claims 29-46 are rejected as being unpatentable over Harrison et al., in view of Yang (US Patent 6,316,019 B1), in view of Durrani (US Patent 6,159,491), in view of Pauletti et al. (US Patent 6,905,701).

The above discussion of Harrison et al. is herein incorporated by reference.

Yang (6,316,019 B1) teach a low temperature process for adding pharmaceutically active compounds to substrates, specifically substrates used in the manufacturer of disposable absorbent articles (column 2, lines 36-45). Claim 1 of the
reference is directed towards a tampon prepared by preparing a solution of an olefinic diol and a pharmaceutically active compound, applying said solution to the disposable absorbent article (column 6). Yang discloses that liquid permeable material may be nonwoven fabric such as a spunbonded fabric, a thermal bonded fabric, a resin bonded fabric, and the like; a three-dimensional or two-dimensional apertured polymeric film; or any other suitable covering surface that is capable of allowing fluid to permeate and be comfortably worn against the perineum (column 5, line 62 to column 6, line 2). Yang teach that a non-limiting list of materials useful as the absorbent material includes cellulosic fibers; synthetic fibers; and superabsorbent polymers such as polyacrylic acid, and the like (column 6, lines 2-7). One of the meanings provided by The Compact Oxford English Dictionary for the word "film" is a "thin layer covering a surface (1 page).

Given its broadest reasonable interpretation, the application of the olefinic diol composition to the substrate i.e. tampon, would reasonably constitute a film coated tampon.

Durrani teach bioadhesive, prolonged release drug composition comprising a synergistic formulation of carrageenan, acrylic acid containing polymers, agarose and an effective amount of a therapeutic agent (column 6, line 10-13). Durrani disclose an embodiment

containing acrylic containing polymer such as polycarbophil, a homopolymer such as acryclic acid and divinely glycol, a copolymer of acrylic acid and a selected C10 to C:30 alkyl acrylate copolymer (column 6, lines 19-26). Durrani teaches that one or more of the therapeutic agents dispersed or dissolved within the bioadhesive, prolonged release drug composition may be selected from drugs, including, for example, anti-inflamatory, antineoplastic or an analgesic agent. Durrani discloses a bioadhesive vaginal gel dosage form designed to incorporate a therapeutic agent for local or systemic action when administered intravaginally.

Pauletti et al (US Patent 6,905,701 82) teach improved formulations for transmucosal vaginal delivery of bisphosphonates comprising from about 0.001 to about 3200 mg of a selected bisphosphonate, from about 0.01 to about 5% hydroxypropyl methylcellulose, from about 40 to about 95% of a selected saturated monoglyceride, diglyceride or triglyceride fatty acids, from about 5 to about 25 % of ethoxydiglycol and, optionally, other pharmaceutically acceptable excipient and additives (column 1, lines 19-32). Pauletti et al. disclose that the formulation is prepared as a vaginal suppository, tablet, bioadhesive tablet, capsule, microparticle bioadhesive microparticle, cream, lotion, foam, film, ointment, solution etc. (column 3, lines 47-54). Pauletti et al. disclose vaginal devices, such as a tampon, tampon-like device, pessary, ring, sponge, strip or cup incorporated with an improved transmucosal vaginal formulation suitable for delivery of bisphosphonates to the systemic circulation (column 3, lines 54-64). Pauletti et al. disclose a tampon drug delivery system in a dehydrated sheathe state (column 5, lines 44-46). Pauletti et al disclose bioadhesive particulate delivery systems consisting of polymers and combinations thereof; it is disclosed that many of these systems were designed for nasal use, but can be easily modified for use in the vagina (column 19, lines 62-65).

In view of the teaching of Pauletti et al. of the improved transmucosal formulations for vaginal drug delivery, someone of skill

in the art would have been motivated to combine the teachings of Harrison et al., and Yang, and Durrani, and
Pauletti et al. to create a device for improved transmucosal drug delivery. Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant claimed invention with a reasonable expectation of success in view of Yang, in view of Durrani, and further in view of Pauletti et al.

Applicants disagree. As stated above, Harrison reference has been disqualified as being by the same inventor and commonly co-owned. Pauletti's reference is similarly disqualified. Durrani discloses gel and there is no gel claimed in the new claims. Yang reference concerns preparation of tampons. Applicants respectfully submit that the new claims would not be obvious from the combination of all four references. In view of the two references being disqualified, a combination of Durrani with Yang does not make the current invention obvious.

It is respectfully requested that the rejections under 35 USC 103 be withdrawn and the new claims passed to issue.

SUMMARY

In summary, Applicants canceled claims 29-46 and added new claim 47-58.

It is believed that the amended claims are in a suitable form for allowance. Notice of Allowance is respectfully requested.

Respectfully submitted,

PETERS VERNY, LLP

Dated: August 10, 2007

Hana Verny (Reg. No. 30,518)

PETERS VERNY, LLP
425 Sherman Avenue, Suite 230
Palo Alto, CA 94306
Tel: (650) 324-1677
Fax: (650) 324-1678
Customer No.: 23308